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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/475,768
Filing Date: December 30, 1999
Appellant(s): RAY, PINAKI

Williams Thomas Babbitt
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 22, 2005 appealing from the Office action mailed December 2, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect. The last sentence states that the claims stand as amended March 18, 2004. This should be August 18, 2004 as was stated in the first sentence.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 12-13 and 48-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boddie (US Pat# 4,192,302) in view of Aigner (US Pat# 4,540,402).

Boddie, in general, discloses a system for fluid isolation in a biological mass having an upstream channel and a downstream channel. The system includes a delivery occlusion conduit that is positioned adjacent the upstream channel, a collection conduit that is positioned adjacent the downstream channel. The perfusion fluid is pumped (pressure device) through the delivery conduit and reclaimed by the collection conduit. The fluid may be a chemotherapeutic agent.

The device has lumens for fluid flow either into or out of the body and is therefore considered capable of being used at any time point, including during diastole and systole. The device having catheters (delivery and collection) sized to enter into blood vessels of the body is thereby capable of being percutaneously positioned via a translumenal route from a first externally accessible channel of a patient. See figure 3.

Specifically, figure 1 of Boddie outlines flow to and from the major organ systems in the body. It is commonly understood that vessels that flow into an organ are considered being

upstream to the organ and conversely vessels taking flow away from are considered downstream to the organ. Looking at figure 1, one can clearly see that the hepatic artery and portal vein are upstream vessels that flow into the liver and while not labeled the hepatic veins are the vessels that receive flow from the liver and return the flow eventually to the heart via the inferior vena cava.

With the above flow scheme in mind, attention is drawn to figure 3 of Boddie. The hepatic artery and portal vein (upstream vessels) are labeled and, as shown, receive branches 35 and 36 of catheter 34. Catheter 34 (delivery conduit) and branches 35 and 36 deliver chemotherapy agents 20 to the liver via these upstream channels. Ligatures T1 and T2 conformably engage and releasably hold (see 3: 30-31) the first branch catheter 35 to the hepatic artery and the second branch catheter 36 to the portal vein, respectively. Each branch 35 and 36 has an opening distal to the ligatures. During placement of the branches and before the ligatures are in place, fluid flow will occur past the catheter branches. Catheter 34 and branches 35 and 36 have a length dimension suitable to be positioned from a first externally accessible channel of a patient (hepatic artery and portal vein are externally accessed by branches 35 and 36 of catheter 34 the proximal end of which resides outside of the patient's body – see figure 3) and then they proceed by way of a translumenal route (see dashed lines indicating catheter branches inside the vessels). Regarding the term percutaneous, the prior art meets this claim term since at some point during the procedure an incision was made through the patient's skin to access the vessels.

Next, Boddie generally refers to means 40 "for selectively isolating the patient's cancer-involved liver". See 2:32-34 of Boddie. Catheter 41 in general shunts blood flow in the inferior vena cava from below the liver to above the liver (see ligatures T3 and T4) via outlet 43 of

catheter 41 positioned in the right atrium of the heart. The important aspect of means 40 is that the region of the inferior vena cava between the ligatures T3 and T4 (collection seals) isolates the flow from the hepatic veins (area of vessel just before T4). Catheter 41 (collection conduit) has opening 44 that collects flow from the isolated region (between ligature T3 and T4) of the inferior vena cava (downstream channel) and returns the flow from the liver to the external flow path. Catheter 41 has a length dimension suitable to be positioned from a first externally accessible channel of a patient (inferior vena cava – see opening in figure 3) and then it proceeds by way of a translumenal route (see dashed lines indicating catheter inside the vessel). Regarding the term percutaneous, the prior art meets this claim term since at some point during the procedure an incision was made through the patient's skin to access the vessel(s).

Boddie meets the claim limitations as described above but fails to include the deliver/collection conduits having collection seals having a dimension to occlude such as elastomeric balloons and the catheters having three lumens.

At the time of the invention, it would have been obvious to substitute balloons for the ligatures of Boddie. Externally mounted balloons on catheter shafts are well known in the catheter art to effectively, less-invasively and safely occlude blood vessels. This is clearly taught by Aigner where the fourth embodiment is designed with a mounted balloon (8) on the front end of the catheter instead of using a ligature. See 3:1-2. "Since making the ligature around the point of the splint catheter is often difficult due to the close proximity of the heart, a preferred embodiment of the invention displays an inflatable balloon in the area of the catheter point; the balloon is mounted from the outside and can be blown up by means of a feed line, **thus creating a seal** within the vessel and making the external ligature unnecessary." [emphasis added] See

4:42-52. The feed line has a lumen (9) with a connection port (10 – seal control mechanism) and is thereby configured to expand and contract the balloon at any time point desired including during diastole and systole, respectively.

Using the same rationale as the Aigner reference, one could obviously reason that when in close proximity of other organs, i.e. the liver as in the case of the Boddie reference, one would want to take the same level of care and use an inflatable balloon in order to provide an occluding device that enhanced the safety to the patient by preventing undue organ damage.

At the time of the invention, it would have been obvious to incorporate two additional lumens into the catheter since the Boddie reference itself teaches a multi-lumen catheter (i.e. the collection conduit (9)) that has fluid, guidewire and inflation lumens. Having these three lumens in one catheter is common in the art since a balloon catheter if being used to transfer fluids will necessitate at least two lumens (i.e. one for fluid and one to inflate the balloon). Additionally, the procedure of using a guidewire to introduce a catheter into the body is also well known in the art and standard practice to ensure proper and safe placement of the device. The motivation for incorporating an inflation lumen and a guidewire lumen would have been to enable the use of a balloon (see paragraph above) and a guidewire thereby providing a device that has been enhanced for safety of the patient both during placement and use.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boddie in view of Aigner.

Boddie in view of Aigner meet the claim limitations as described above but fail to include the biological mass being the human heart. At the time of the invention, it would have been obvious to use the invention of Boddie to isolate and perfuse the human heart during

procedures such as bypass where the delivery conduit would be positioned into the aorta and the collection conduit would be positioned into the coronary sinus.

Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently that the prior art device, the claimed device was not patentably distinct from the prior art device.

Furthermore, the biological mass, i.e. human heart of claim 10, is functionally claimed in claim 1. Claim 1 recites "**for fluid isolation** in a biological mass". [Emphasis Added] Therefore, the prior art structure, upon meeting the structural limitations of the claims, only has to be capable of performing the recited function in order to meet the functional limitations of the claims. Looking to applicant's claim language, each conduit has to be suitable in length "to be positioned from a first/second externally accessible channel". However, the functional language does not set forth the exact location of this first/second externally accessible channel other than somewhere along the length of the aorta and coronary sinus. Like the procedure set up in figure 3 of Boddie, the device of Boddie is capable of being used in an open chest cavity procedure on a human heart. Catheter 35 of Boddie and balloon 8 of Aigner are structured to be inserted into and occlude a human vessel; therefore catheter 35 and balloon 8 could be used for positioning in and occlusion of the aorta and coronary sinus of a heart. Additionally, the function claim language does not specify the type of human heart, i.e. a neonatal, an artherosclerotic, or from a 7.5' person. These functional recitations to be met are vague and the device of Boddie is capable of being externally inserted into and positioned in at least one aorta and coronary sinus at some

point along the vessels and being translumenally positioned near a human heart of a least one patient whether they be neonate or artherosclerotic.

Claims 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boddie in view of Aigner in further view of Sterman et al (USPN 5,452,733).

Boddie in view of Aigner meets the claim limitations as described above but fails to include the biological mass being the heart, the first externally accessible channel being a femoral artery and a second externally accessible channel being the jugular vein.

However, Sterman discloses a method for accessing the heart and includes placing a catheter into the aorta via the femoral artery and placing a catheter into the coronary sinus via the jugular vein. See Detailed Description paragraphs 14,15 and 18. This double placement of occlusion balloon catheters enable either antegrade or retrograde fluid delivery with a minimally invasive approach of accessing the heart. See Summary.

At the time of the invention it would have been obvious to incorporate the method and route of balloon catheter placement into the invention of Boddie in view of Aigner. The motivation for selecting the heart as the biological mass would have been since heart bypass procedures require devices having the structure of the invention of Boddie in view of Aigner and would have been done in order to use the device in an additional application that utilizes its intended function. Additionally, the motivation for the incorporation of the vessel insertion as taught by Sterman would have been in order to provide a minimally invasive procedure (as taught by Sterman, above) to enhance the safety to the patient.

Furthermore, the first and second accessible channels, i.e. femoral artery, radially artery and jugular vein of claims 61-64, are functionally claimed in claims 1 and 48. Claims 1 and 48 recite "**to be positioned** from a first externally accessible channel...**to be positioned** from a second externally accessible channel". [Emphasis Added] Therefore, the prior art structure, upon meeting the structural limitations of the claims, only has to be capable of performing the recited function in order to meet the functional limitations of the claims. These functional recitations are vague. The claims do not set forth where along the femoral/radial artery or jugular vein the externally accessible site is located. The claims do not set forth the organ for isolation, i.e. brain or kidney. The claims do not set forth the type of patient these vessels are located in, i.e. a neonate, an artherlosclerotic elderly person, a rat or an elephant. Clearly, the catheter of Boddie with the occlusion balloon of Aigner is capable of being inserted in at least one patient, whether they be neonate or rat, where the insertion site in the femoral artery/jugular vein is located so that conduit 34/conduit 33 can translumenally be positioned in and occlude an upstream/downstream channel of a kidney.

(10) Response to Argument

Claim 1:

Appellant argues that Boddie in view of Aigner does not describe a delivery conduit and a collection conduit each having a length dimension suitable to be positioned by way of a percutaneous translumenal route. See page 7 line 5+ of Appeal Brief. This argument is not persuasive since the length being claimed is based on the functioning of the device and the functional language in the claims is vague.

As long as the prior art meets the claim limitations and is capable of performing the recited function, then the prior art meets the claimed invention. Boddie in view of Aigner discloses both an upstream and downstream catheter (35 and 41, respectively). Both of these catheters have a length. See figure 3. If one includes the proximal portion of each catheter (34 and 33, respectively) then each catheter has a longer length. Clearly, Boddie in view of Aigner meet the structural limitations of the claims.

Regarding the functional recitation of a length "to be positioned by way of a percutaneous translumenal route", this language does not further limit a specific length. The functional language does not impart the location of an insertion site, specify the organ, specify the type of patient or allude to the distance from the insertion site to the organ of interest.

Appellant argues that the procedure depicted in figure 3 of Boddie , i.e. opened-chest procedure, does not make the blood vessel "externally accessible". See page 7 line 10+ of Appeal Brief. It is Appellee's position that the procedure shown in figure 3 of Boddie makes the blood vessels accessible by anyone or anything normally external to the body.

Externally is defined by *The American Heritage® Dictionary of the English Language, Fourth Edition* on-line version at http://dictionary.reference.com/search?q=externally%20 as

1. Relating to, existing on, or connected with the outside or an outer part; exterior.
2. Suitable for application to the outside: *external paints.*
3. Existing independently of the mind.
4. Acting or coming from the outside: *external pressures.*
5. Of or relating chiefly to outward appearance; superficial: "An internal sense of righteousness dwindles into an external concern for reputation" (A.R. Gurney, Jr.).

6. Of or relating to foreign affairs or foreign countries: *the country's minister of external affairs.*

Accessible according to *The American Heritage® Dictionary of the English Language, Fourth Edition* on-line version at http://dictionary.reference.com/search?q=accessible is defined as

1. Easily approached or entered.
2. Easily obtained: *accessible money.*
3. Easy to talk to or get along with: *an accessible manager.*
4. Easily swayed or influenced: *accessible to flattery.*

Using the definitions above, one can understand that "externally accessible" imparts that the vessel can be easily approached or entered from the outside. Clearly, the open-chest procedure as shown in figure 3 of Boddie makes the vessels of the chest cavity easily approached from the outside since each vessel is in plain view.

Appellant further argues that Boddie in view of Aigner does not render obvious the claims because there is no motivation to combine the teaching of the two references. See page 7 line 14+ of Appeal Brief. This is not persuasive because Appellant completely ignores the motivation that was provide in the original rejection. See Final Office Action page 4 lines 12-page 5 line 6 and page 5 above. The Aigner reference provides the motivation in that positioning ligatures around vessels can present a problem by potentially damaging surrounding organs and that an occlusive balloons solve this problem. See Aigner 4:42-52.

Appellant only comments about the Boddie reference and branching of catheters but these comments do not pertain to the actual combination of the references. Appellant also comments about other ligatures in the Boddie reference but these comments also do not pertain to the actual combination of the references.

Claim 48:

Appellant provides the same arguments for claim 48 as for claim 1 above.

Claims 10-11:

Appellant argues that for the same reasons claim 1 is not met by Boddie in view of Aigner, claims 10-11 are not. Appellant also argues that Boddie in view of Aigner isolate the liver. However, the claims recite "**for** fluid isolation in a biological mass". [Emphasis Added] This recitation is functional and the prior art only has to meet the structural limitations of the claim and be capable of performing the function to read on the claimed invention. As stated above, see page 7, the prior art is capable of performing the function.

Claims 61-64:

Appellant argues that for the same reasons as claims 1 and 48 are not met by Boddie in view of Aigner, claims 61-64 are not. Appellant also argues that Boddie in view of Aigner in further view of Sterman provides no motivation for positioning the delivery conduit in either the femoral artery or the radial artery and positioning the collection conduit in the jugular vein. Appellant is reminded that this recitation is functional and the prior art only has to meet the

structural limitations of the claim and be capable of performing the function to read on the claimed invention. As stated above, see page 9, the prior art is capable of performing the function.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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